



Attorney Docket No. 9233-54

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Ekwuribe et al.

Application Serial No.: 09/873,899

Filed: June 4, 2001

For: *MIXTURES OF INSULIN DRUG-OLIGOMER CONJUGATES COMPRISING POLYALKYLENE GLYCOL, USES THEREOF, AND METHODS OF MAKING*

**Declaration of Nnochiri N. Ekwuribe
Under 37 C.F.R. § 1.132**

Sir:

I, Nnochiri N. Ekwuribe, hereby declare as follows:

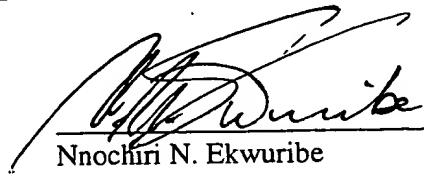
1. I am a named co-inventor on U.S. Patent Application Serial No. 09/873,899, entitled "Mixtures of Insulin Drug-Oligomer Conjugates Comprising Polyalkylene Glycol, Uses Thereof, and Methods of Making" ("the '899 application"), filed June 4, 2001. The other co-inventors on this application are Christopher H. Price, Aslam M. Ansari and Amy Odenbaugh.
2. I am also a named co-inventor on U.S. Patent Application Serial No. 10/075,097, entitled "Methods of Treating Diabetes Mellitus" (the '097 application"), filed February 13, 2002 and claiming priority under 35 U.S.C. § 119(e) to provisional application serial number 60/269,2001, filed February 15, 2001. The other co-inventors on this application are Christopher H. Price, James Gordon Still and Jennifer Ann Filbey. Additional co-inventors Aslam M. Ansari, Amy L Odenbaugh and Balasingam Radhakrishnan have been added to this application as set forth in a Request to Correct Inventorship Under 37 C.F.R. § 1.48(c), a copy of which is attached hereto.
3. The '097 application was published by the U.S. Patent and Trademark Office as Publication No. US 2003/0050228 A1 on March 13, 2003. This publication is the basis for a rejection under 35 U.S.C. § 102(e) of pending claims 1-3, 7-11, 17, 29, 30,

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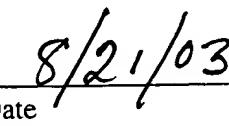
40, 41, 46-48, 50 and 52 in the '899 application because the '097 application, including claims 170, 183 and 186, allegedly teaches and claims monodispersed mixtures of an insulin drug-oligomer conjugate where the oligomer is C(=O)-(CH₂)₅-OC₂H₄)₇-OCH₃ attached to Lys^{B29}. The qualification of the '097 application publication as prior art against the instant claims is stated in the June 6, 2003 Office Action to be on the basis that the disclosure of the monodispersed mixtures is supported by the disclosure of the provisional application upon which it claims priority and because the inventorship of the '097 application is different from the inventorship of the instant application.

4. The subject matter of the '097 application upon which the Examiner is relying in support of the 35 U.S.C. § 102(e) rejection of claims in the '899 application was invented by Nnochiri N. Ekwuribe, Christopher H. Price, Balasingam Radhakrishnan, Aslam Ansari and Amy L. Odenbaugh.
5. The subject matter of claims 1-3, 7-11, 17, 29, 30, 40, 41, 46-48, 50 and 52, which are rejected under 35 U.S.C. § 102(e) in the '899 application was invented by Nnochiri N. Ekwuribe, Christopher H. Price, Balasingam Radhakrishnan, Aslam Ansari and Amy L. Odenbaugh.
6. Thus, the inventors of the subject matter of the '097 application upon which the Examiner is relying and the inventors of the subject matter of the claims rejected under 35 U.S.C. § 102(e) in the '899 application are the same.
7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

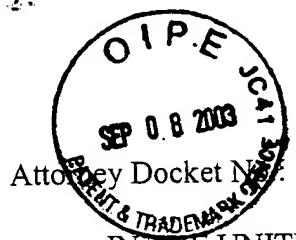
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Nnochiri N. Ekwuribe



Date 8/21/03



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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Ekwuribe et al.

Application Serial No.: 60/269,198

Group Art Unit: 1646

Filed: February 13, 2002

For: Methods of Treating Diabetes Mellitus

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**REQUEST TO CORRECT INVENTORSHIP
UNDER 37 C.F.R. § 1.48(a) AND 35 U.S.C. § 116**

Sir:

Pursuant to 37 C.F.R. § 1.48(a), please add the following inventors to the above-referenced patent application:

Aslam M. Ansari
19651 Club Lake Road
Montgomery Village, MD 20886
U.S. citizen

Amy L. Odenbaugh
4023 Quail High Boulevard
Morrisville, NC 27560
U.S. citizen

Balasingam Radhakrishnan
209 Faison Road
Chapel Hill, NC 27517
U.S. citizen

In support of this request are included:

- (a) A fee as set forth in 37 C.F.R. § 1.17(i);
- (b) Verified statements by Aslam M. Ansari, Amy L. Odenbaugh, and Balasingam Radhakrishnan that the error in inventorship arose without any deceptive intent on the part of these individuals;
- (c) A Consent of Assignee executed by the assignee; and

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(d) An executed Declaration and Power of Attorney.

The joint inventors, Nnochiri Nkem Ekwuribe, Christopher H. Price, James Gordon Still, and Jennifer Ann Filbey, are properly named as inventors on the above-referenced application. However, applicants became aware that the three inventors to be added herein are also inventors of the invention currently claimed in the application, so that more than all of the currently named inventors are the actual inventors of the invention being claimed in the application.

Therefore, it is respectfully requested that the above-named inventors be added in order to correct the inventorship in this application.

Respectfully submitted,

Mary L. Miller
Registration No. 39,303

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec
Post Office Box 37428
Raleigh, North Carolina 27627
Telephone: 919/854-1400
Facsimile: 919/854-1401

Certificate of Mailing under 37 § CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on _____, 2003.

Cathy A. Schetzina



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PATENT

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Filed: June 4, 2001

For: *MIXTURES OF INSULIN DRUG-OLIGOMER CONJUGATES COMPRISING POLYALKYLENE GLYCOL, USES THEREOF, AND METHODS OF MAKING*

**Declaration of Balasingam Radhakrishnan, Ph.D.
Under 37 C.F.R. § 1.131 and *In re Katz*¹**

Sir:

I, Balasingam Radhakrishnan, Ph.D. hereby declare as follows:

1. I am the Director of Chemistry Development and Manufacturing at Nobex Corporation located in Research Triangle Park, N.C.
2. I am a named co-inventor on U.S. Patent Application Serial No. 09/873,899 entitled, "Mixtures of Insulin Drug-Oligomer Conjugates Comprising Polyalkylene Glycol, Uses Thereof, and Methods of Making" (*hereinafter*, "the '899 application"), filed June 4, 2001.
3. The subject matter of the application was invented by Nnochiri N. Ekwuribe, Christopher H. Price, Aslam M. Ansari, Amy L. Odenbaugh and myself. Each of us is named as an inventor on the '899 application.
4. Radhakrishnan et al. Stability and Physical Characteristics of Orally Active Amphiphilic Human Insulin Analog, Methoxy (Polyethylene Glycol) Hexanoyl Human Recombinant Insulin (HIM2). The 27th International Symposium on Controlled Release of Bioactive Materials and the Third Consumer and Diversified Products Conference, July 7-13, 2000, was co-authored by one of the Inventors,

¹ 687 F.2d 450, 215 U.S.P.Q. 14 (C.C.P.A. 1982).

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Balasingam Radhakrishnan, and two additional authors: J.S. Rajagopalan and J. Burnham.

5. Some of the experiments described in the Radhakrishnan et al. reference were conducted by J.S. Rajagopalan and J. Burnham. These experiments were under the direction and supervision of one or more of the Inventors.
6. Amy L. Odenbaugh is not an author on the Radhakrishnan et al. reference.
7. The authors named on the Radhakrishnan et al. reference who are not included as inventors on the above-captioned patent application did not contribute to the conception of the claimed invention set forth in the above-captioned patent application.
8. For the reasons set forth above, the inventors named on the above-captioned patent application are the true inventors thereof.
9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Balasingam Radhakrishnan
Balasingam Radhakrishnan, Ph.D.

08 | 13 | 03
Date